510 (k) Summary

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: October 24, 2002

510(k) number: K023601

NOV 1 9 2002

Applicant Information:

Rubicor Medical, Inc.
849 Veterans Blvd.
Redwood City, CA 94063

Contact Person: Ary Chernomorsky
Phone Number: (650) 556-1070
Fax Number: (650) 556-1821

Device Information:

Classification: Class II
Trade Name: Rubicor EnCapsule™ Breast Biopsy Device
Classification Name: Electrosurgical Device and accessories (21 CFR 870.4400)

Equivalent Device:

The subject device is substantially equivalent in intended use and/or method of operation to the Rubicor Breast Biopsy Device (K020047)

Intended Use:

The Rubicor EnCapsule™ Breast Biopsy Device is intended for diagnostic sampling of breast tissue during breast biopsy procedure.
The Rubicor EnCapsule™ Breast Biopsy Device is to be used for diagnostic purposes only and is not intended for therapeutic uses.

Test Results:

Performance

Results of in-vitro testing demonstrate that Rubicor EnCapsule™ Breast Biopsy Device is safe and effective for its intended function.

Biocompatibility

The materials used in the Rubicor EnCapsule™ Breast Biopsy Device have been shown to be biocompatible.

Summary:

Based on the intended use, product, performance and biocompatability information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed and unmodified predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 9 2002

Rubicor Medical, Inc.
Robert J. Chin, Ph.D.
Regulatory Consultant
849 Veterans Boulevard
Redwood City, California 94063

Re: K023601
Trade/Device Name: Rubicor Encapsule Breast Biopsy Device, Model 30086
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 24, 2002
Received: October 28, 2002

Dear Dr. Chin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use Statement

510(k) Number (if known): K023601

Device Name: Rubicor EnCapsule™ Breast Biopsy Device

Indications for Use:

The Rubicor EnCapsule™ Breast Biopsy Device is intended for diagnostic sampling of breast tissue during breast biopsy procedure.

The Rubicor EnCapsule™ Breast Biopsy Device is to be used for diagnostic purposes only and is not intended for therapeutic uses.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023601

Prescription Use ✓ OR Over-the Counter Use _____
(Per 21 CFR 801.109)